

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

Pamela R. Cooper and David L. Cooper, h/w	:	
	:	
Plaintiffs,	:	<b>C.A.:</b>
	:	
v.	:	
	:	
BKC Pain Specialists, Adil Katabay, M.D., Barry J.	:	<b>COMPLAINT AND</b>
Cadden, Gregory Conigliaro, Lisa Conigliaro Cadden,	:	<b>JURY DEMAND</b>
Douglas Conigliaro, Carla Conigliaro, and Glenn A.	:	
Chin, Ameridose, LLC, GDC Properties Management,	:	
LLC, Medical Sales Management, Inc., Medical Sales	:	
Management SW, Inc., and ARL Bio Pharma, Inc. D/B/A	:	
Analytical Research Laboratories,	:	
Defendants.	:	
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Plaintiffs, by and through undersigned counsel, and for their Complaint against Defendants, allege upon information and belief as follows:

**TABLE OF CONTENTS**

I.	INTRODUCTION .....	2
II.	PARTIES .....	4
III.	JURISDICTION AND VENUE.....	8
IV.	STATEMENT OF THE FACTS .....	9
	A. RELEVANT BACKGROUND .....	9
	B. THE NECC RELATED DEFENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY .....	21
	C. THE NECC RELATED DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS .....	25
	D. DEFENDANTS EXPOSED PLAINTIFF TO TOXIN CONTAMINATED NECC COMPOUNDED MPA.....	26

V.	SUBSTANTIVE COUNTS AGAINST THE NECC RELATED DEFENDANTS AND ARL .....	30
	COUNT I - NEGLIGENCE UNDER MASSACHUSETTS OR OTHER APPLICABLE STATE LAW .....	30
	COUNT II - NEGLIGENCE <i>PER SE</i> .....	33
	COUNT III – NEGLIGENT SUPERVISION .....	34
	COUNT IV – STRICT PRODUCTS LIABILITY: DEFECTIVE MANUFACTURING LIABILITY UNDER THE OHIO PRODUCTS LIABILITY ACT (O.R.C § 2307.74 <i>ET SEQ.</i> ) .....	37
	COUNT V – STRICT PRODUCTS LIABILITY: LIABILITY UNDER THE OHIO PRODUCTS LIABILITY ACT FOR INADEQUATE WARNING OR INSTRUCTION (O.R.C. § 2307.76 <i>ET SEQ.</i> ) .....	38
	COUNT VI – STRICT PRODUCTS LIABILITY: DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS (O.R.C. § 2307.77 <i>ET SEQ.</i> ) .....	40
	COUNT VII – BREACH OF IMPLIED WARRANTY AND TORTIOUS BREACH OF WARRANTY .....	42
	COUNT VIII - PUBLIC NUISANCE .....	43
	COUNT IX-DECEPTIVE TRADE AND BUSINESS PRACTICES ACT VIOLATIONS ..	44
	COUNT X– CONCERTED ACTION AND CIVIL CONSPIRACY .....	48
	COUNT XI – PUNITIVE DAMAGES.....	49
VI.	SUBSTANTIVE COUNTS AGAINST THE BKC PAIN SPECIALISTS DEFENDANTS .....	50
	COUNT XII – MEDICAL NEGLIGENCE .....	50
	COUNT XIII – LACK OF INFORMED CONSENT .....	54
VII.	SUBSTANTIVE COUNTS AGAINST ALL DEFENDANTS .....	56
	COUNT XIV - LOSS OF CONSORTIUM CLAIMS ON BEHALF OF SPOUSE PLAINTIFF DAVID L. COOPER.....	56
	PRAYER FOR RELIEF .....	57
	JURY DEMAND .....	57

## I. INTRODUCTION

1. In 2012, a widespread outbreak of fungal meningitis injured people in more than 20 states and has caused scores of deaths as of the time of the filing of this Complaint. At a minimum, over 750 people have been diagnosed with serious illnesses and thousands more live in fear of contracting the disease and the prospect of suffering painful injuries, testing and

treatment. This preventable outbreak originated from a medication compounded and distributed by the now bankrupt New England Compounding Pharmacy, Inc., d/b/a/ “New England Compounding Company” (“NECC”), that was improperly compounded, sterilized, tested, packaged, marketed, labeled, dispensed, acquired, prescribed and administered by the various defendants named herein.

2. The Food and Drug Administration (“FDA”) and the Centers for Disease Control (“CDC”) identified fungus in lots of NECC supplied injectable steroids, specifically methylprednisolone acetate (“MPA”) and other drugs. The FDA and CDC concluded that the MPA, which was compounded at the NECC facility in Framingham Massachusetts, was the cause of the aforementioned injuries and deaths. The NECC facilities, and especially its so called “clean room”, were deplorably unclean and unsterile and were the source of fungus that contaminated vials holding NECC’s compounded medications. The blatant uncaring and disregard for even the most basic sterility obligations by NECC and the various defendants named herein, their respective wanton disregard for the requirements of their professions, licenses and undertakings, their respective conscious disregard for safety standards, NECC’s deplorable facility conditions and blatant contempt for prior complaints, adverse events, and inspection findings, along with other Defendants’ woefully insufficient inspection and due diligence testing, inadequate warning, overt misrepresentations, and knowing distribution of drugs compounded under the spectre of such wrongful conduct, all led and substantially contributed to a national epidemic of fungal meningitis, as well as were substantial contributing factors to Plaintiffs’ injuries and losses described below.

3. Multiple vials of MPA, along with other medications compounded at the NECC facilities have been recalled, but the recall was too late for Plaintiffs, and for many others who

suffered serious, and catastrophic injuries or death from one of the largest iatrogenic epidemics' in United States' history.

## II. PARTIES

4. Plaintiff Pamela R. Cooper ("**Plaintiff**") and David L. Cooper ("**Spouse Plaintiff**") (collectively "**Plaintiffs**") are married and at all times relevant have jointly resided at 86 Village Gate Boulevard, Delaware, OH 43015.

5. During all relevant times, defendant BKC Pain Specialists, LLC ("**BKC**") was an Ohio Medical Limited Liability Company organized and licensed to conduct business in the State of Ohio with a principle place of business at 1065 Delaware Avenue, Suite A, Marion, Ohio 43302.

6. At all relevant times, Defendant Adil Katabay, M.D. ("**Katabay**"), was a physician licensed to practice medicine in the State of Ohio holding himself out to the public as being "well-known for treating the most complex and challenging cases of chronic pain." <http://bkcpainspecialists.com/doctors.htm> and "offer[ing] the latest state-of-the-art therapeutic options, including epidurals, trigger point injections, joint injections, nerve blocks, and radio-frequency for pain management." *Id.* Defendant Dr. Katabay at all times material herein was employed by, associated with and/or was an owner, member or shareholder of the medical practice conducted by Defendants BKC under the trade name "BKC Pain Specialists."

7. At all times relevant herein, Defendants Katabay and/or BKC (collectively "**BKC Pain Specialist Defendants**") received and treated patients for consideration, including Plaintiff.

8. Defendant Ameridose, LLC, ("**Ameridose**") is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 203 Flanders Road, Westborough, Massachusetts, 01581. The

managers of Ameridose are Defendants Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Defendant Gregory Conigliaro.

9. Defendant GDC Properties Management, LLC, ("**GDC**") is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with its principle place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc., ("**MSM**") is a Massachusetts corporation organized and originated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant Douglas Conigliaro is the President and a Director of MSM and in such capacity actively participated in, controlled and/or directed its operations and activities. Defendant Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc., ("**MSMSW**") is a Massachusetts corporation organized and originated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant Barry J. Cadden ("**Barry Cadden**") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093, and is a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of NECC. At least until

October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by Massachusetts' regulation, 247 CMR 2.00, and upon information and belief, he compounded MPA at NECC. Barry Cadden was also a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations. Barry Cadden was also the Treasurer and Director of MSM and MSMSW.

13. Defendant Gregory Conigliaro ("**Gregory Conigliaro**") is an individual person residing at 1 Mountain View Drive, Framingham, Massachusetts 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, Registered Agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw operations, and regularly appeared in the NECC facility. Gregory Conigliaro is also the founder and a Manager of Ameridose and involved in Ameridose's day-to-day operations. Gregory Conigliaro is also Secretary and Director of MSM and MSMSW.

14. Defendant Lisa Conigliaro Cadden ("**Lisa Cadden**") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.

15. Defendant Douglas Conigliaro ("**Douglas Conigliaro**") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Douglas Conigliaro is Director and President of MSM and MSMSW. Douglas Conigliaro provided advice, oversaw day-to-day operations and regularly appeared in the MSM/MSMSW facility.

16. Defendant Carla Conigliaro (“**Carla Conigliaro**”) is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Carla Conigliaro is one of the Directors of NECC and the wife of Douglas Conigliaro.

17. Defendant Glenn A. Chin (“**Glenn Chin**”) is an individual person residing at 173 Mechanic Street, Canton, Massachusetts 02021. At least until October 2012, Glenn Chin was a pharmacist at NECC. Chin, upon information and belief, compounded drugs, including MPA, at NECC.

18. Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Chin, Ameridose, LLC, GDC Properties Management, LLC, Medical Sales Management, Inc., Medical Sales Management SW, Inc., are sometimes collectively referred to as the “**NECC Related Defendants.**”

19. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories (“**ARL**”) is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principle place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

20. At all times material herein, defendants acted by and through their respective agents, officers, employees and servants, actual, apparent or ostensible, any and all of whom were then and there acting within the course and scope or their agency, authority, duties or employment.

### III. JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1334(b) because, as described herein, each claim asserted herein is related to a pending bankruptcy proceeding filed by NECC under title 11.

22. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code which is pending and captioned as *In re: New England Compounding Pharmacy, Inc., Debtor*, United States Bankruptcy Court for the District of Massachusetts Case No. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

23. This case is related to NECC's Bankruptcy case because the prosecution and/or outcome of the proceeding could have an effect on the bankruptcy estate.

24. Upon information and belief, (i) NECC has express contractual indemnification obligations to among others, the NECC Related Parties, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, GDC, MSM and MSMSW, (ii) some if not all of the aforementioned individuals are insureds under NECC's insurance policies and (iii) NECC and the NECC Related Parties, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, GDC, MSM and MSMSW, all have contribution, indemnification and/or other reimbursement claims against each other.

25. Adversary proceedings seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against several of the NECC Related Defendants (Barry Cadden, Lisa Cadden, Gregory Conigliaro, Carla Conigliaro, GDC, and MSM).

26. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings (the “MDL Court”). The transferred actions are pending in the MDL Court in the Multidistrict Litigation action styled: *In re: New England Compounding Pharmacy, Inc. Products Liability Litigation*, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination. This case is a related case to those and subject to transfer to the MDL per order of the MDL Court relating to transfer of cases related to the NECC MDL and Chapter 11 Bankruptcy.

27. Venue lies initially in this District Court as Plaintiffs and two of the defendants are citizens of Ohio and reside or are headquartered in this District, and this court has *in personam* jurisdiction over all defendants under the jurisdictional laws of Ohio based on the circumstances pleaded below.

#### **IV. STATEMENT OF THE FACTS**

##### **A. RELEVANT BACKGROUND**

28. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to pharmacies in many states throughout the United States, including Ohio.

29. Upon information and belief, NECC was a privately-held company that was owned and controlled by Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Barry Cadden, and Lisa Cadden. At all times material these defendants had the ability and power to

affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter.

30. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden also was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including MPA, at NECC.

31. "Manager of Record" or "Pharmacist Manager of Record," as defined by Massachusetts Regulation, 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

32. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

33. At least until October 2012, Gregory Conigliaro was involved in co-managing the day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC. At all times material herein he had the ability and power to affect changes and corrective actions relating to these entities' conduct and omissions that are relevant to this matter.

34. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC. She also was involved in the management of NECC and had the ability and power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter.

35. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC. At all times material herein Chin had the ability and power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter, and/or or take reasonable steps and measures to prevent or ameliorate any harm happening to consumers by NECC's conduct and omissions that are relevant to this matter.

36. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution center to entities of common ownership - currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

37. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

38. On April 11, 2011, Ameridose employee, Michelle Rivers, upon information and belief at the direction of the NECC principals, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

39. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact "mlord@medicalsalesmgmt.com." Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

40. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

41. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW has reportedly stated: "I didn't think there was any difference [between Ameridose and NECC]."

42. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

43. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

44. According to defendant ARL's Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

45. According to ARL's Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

46. Defendant ARL also states on its Internet website that it follows “USP monographs/general chapters[,]” and that it has a formal Quality Assurance Program in compliance with “USP monographs/general chapters[.]”

47. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: “[y]our customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. *You should expect nothing less from the testing laboratory you entrust.*” (*emphasis is original*).

48. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL’s “[t]esting methods and technologies [are] unparalleled in the market today[.]” (*emphasis in original*).

49. Upon information and belief, ARL provided and was paid for sterility testing services and information to NECC for its compounded medications, including MPA.

50. With respect to its sterility tests, ARL, on its Internet website, states: “We examine each sterility test for growth at days 2, 3, 7 and 14 and log the results. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation.”

51. At all times material herein, Defendant ARL knew or had reason to know that (a) its testing and test results relating to NECC products, including MPA, were commissioned and intended for the protection of patients who were to be administered NECC’s compounded medications; (b) that its test results would be relied upon and used by NECC in dispensing the medication to doctors and medical facilities ordering and administering NECC’s medications; (c) that doctors and NECC would distribute or share ARL’s test results with physicians and/or

hearth care facility decision makers in connection with NECC's marketing and/or dispensing of its compounded medications, including MPA.

52. Defendant GDC, whose name is an acronym for "Gregory D. Conigliaro," owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

53. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

54. In an online posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC describes one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state ...rules and regulations."

55. GDC maintained and/or exercised a high degree of control over the premises leased by NECC.

56. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden and Glenn Chin compounded, tested, marketed, dispensed and/or distributed MPA, including a purported preservative free sterile version that is difficult to compound and carries substantial risks of contamination, adulteration and/or misbranding.

57. MPA is a steroid medication that is used, *inter alia*, to treat joint, neck and back pain. MPA is commonly administered via spinal-area injection to patients with neck and back pain.

58. GDC and Gregory Conigliaro knew that NECC was compounding MPA, including a purported preservative free version, at NECC's 697 Waverly Street facility, and further knew that this medication was injected into humans and was required to be sterile.

59. Until October 2012, NECC compounded MPA, including a preservative free version, at its facility in Framingham, Massachusetts, and NECC sold MPA, including a preservative free version, to healthcare providers in more than 20 states across the country, including Ohio, directly and/or through Ameridose, MSM and/or MSMSW

60. On September 21, 2012, the CDC was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

61. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and is usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

62. According to the CDC, symptoms for meningitis include the following: new or worsening headache, fever, sensitivity to light, stiff neck, new weakness or numbness in any part of the body, slurred speech and increased pain, redness or swelling at the injection site. Death may result from meningitis.

63. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients may just exhibit one or two of these symptoms.

64. On or about September 26, 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013. The “PF” denotes preservative free. The number in the Lot# denotes the date of the lot’s compounding.

65. The FDA identified BKC Pain Specialists, LLC in Marion, Ohio as one of the healthcare facilities that received vials of MPA that were subject to the September 2012 recall. BKC Pain Specialists, LLC is also the location where Plaintiff was injected with NECC’s MPA on or about September 24, 2012 and October 1, 2012. On information and belief, Plaintiff was administered MPA from one of the recalled lots

66. On October 6, 2012, NECC announced that it was recalling “all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts.”

67. In NECC’s October 6, 2012, press release, NECC advised that it was “notifying its customers of this recall by fax[,]” and that “[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice.”

68. In NECC’s October 6, 2012, press release, NECC explained that “[p]roducts from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo.

69. In addition, as the CDC, and other health care authorities, practitioners and commentators monitored and reported on developments in the exposed patient community, it was discovered that the problems associated with patient injections from the three recalled MPA lots are manifold, latent, insidious and long lasting, including: (a) an outbreak of localized spinal or paraspinal infections at or about the site where the MPA steroid was injected; (b) infections associated with injections into a peripheral joint space, such as a knee, shoulder, or ankle; and (c) delayed manifestation, recrudescence and relapse of diagnosed fungal meningitis and spinal, paraspinal and joint space infections and abscesses.

70. On or about October 3, 2012, the Massachusetts Department of Public Health (“DPH”) secured the surrender of NECC’s license to operate as a compounding pharmacy.

71. On or about October 8, 2012, at the request of DPH, defendants Barry Cadden and Glenn Chin agreed to voluntarily cease their practice as pharmacists until at least December 31, 2012. Defendant Lisa Cadden also has agreed to voluntarily cease her practice as a pharmacist until at least December 31, 2012. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

72. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, “[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation.”

73. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

74. From May, 2012 through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC in one lot on May 21, 2012.

75. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

76. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

77. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

78. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials from Lot #08102012@51, BUD 2/6/2013.

79. The Microbiology Reports issued by ARL to NECC between May, 2012 and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were to be conducted in compliance with USP 71.

80. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

81. ARL was well aware of the sterility risks posed by compounding pharmacies, specifically including the sterility risks posed by NECC's compounding practices.

82. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

83. In 2005, ARL's Chief Executive Officer, Thomas Kupiec ("Kupiec"), wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

84. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

85. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[.]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions." All defendants either knew or had reason to know of this FDA guidance publication.

86. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to

be tested in relation to the number of articles in the batch” and a “14-day quarantine of the drug to await final test results[.]” Kupiec wrote in a 2007 published article that there should be “separate standards for compounding pharmacies and manufacturers.”

87. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec’s 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

88. On information and belief, other testing laboratories that perform sterility testing on drugs compounded by compounding pharmacies request double the number of samples required by USP 71.

89. Between January 2012 and August 2012, NECC’s environmental monitoring program for its compounding facility yielded findings of numerous microbiological isolates (bacteria and mold) within the so called “Clean Room” at NECC’s facility used for the production of MPA. Defendants NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin knew or should have known of these findings.

90. Defendants NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to investigate the findings, cause(s) and source(s) of these isolates and made no effort to identify the isolates.

91. Defendants NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin

failed to perform any product assessments for the products made in the “Clean Room” where the isolates were found.

92. Defendants NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to take any corrective actions or measures with regards to the isolates that were found.

93. Despite the findings of these isolates, NECC continued to compound preservative free MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

**B. THE NECC RELATED DEFENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY**

94. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations at NECC that placed the public’s health and safety at risk. Each Agency has released reports on Defendants’ longstanding widespread disregard for safety. Some examples follow. The conditions were so bad, the FDA issued a Form 483 identifying eight pages of observed conditions or practices that may indicate violations of the Federal Food, Drug and Cosmetic Act, or related regulations. The findings reveal repulsive conditions where bacteria and mold fester throughout the NECC facility and equipment.

95. In early October 2012, FDA investigators located fungal contamination in a sealed vial of MPA at NECC’s facilities on GDC’s property. The FDA’s findings prompted NECC to recall 17,676 single-dose vials of MPA.

96. Even though NECC recalled the MPA in early October, thousands (estimated to be over 14,000) of people at outpatient clinics and similar facilities in more than 20 states were injected with the steroid between July and September 2012, including Plaintiff.

97. The Massachusetts Department of Public Health (DPH) investigators, in collaboration with investigators from the FDA, investigated NECC and released preliminary findings on October 23, 2012.

98. As an initial matter, the DPH stated: “[u]pon beginning the joint on-site investigation of NECC early in this outbreak, DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public’s health and safety at risk.”

99. In its preliminary findings the DPH found: “[d]uring the facility inspections, investigators documented serious health and safety deficiencies related to the practice of pharmacy.” The DPH noted:

1. NECC distributed two of the recalled lots of methylprednisolone acetate (PF) 80 MG/ML prior to receiving results of sterility testing:

a. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were made prior to the final sterility tests results being received.

b. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. Eleven shipments of product were made prior to the final sterility tests results being received.

2. Final sterilization of product did not follow proper standards for autoclaving (sterilization through high pressure steam) pursuant to United States Pharmacopeia Standard 797 (“USP 797”) and NECC’s own Standard Operating Procedures. Examination of NECC records indicated a systemic failure to keep products in the

autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

3. NECC did not conduct proper validation of autoclaves pursuant to USP 797. NECC failed to test their autoclaves to ensure proper function.

4. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot 08102012@51.

5. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 797. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.

6. Condition of “Tacky” mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

7. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: “A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending.”

101. The inspection reports further revealed that surface samples from NECC’s “clean” rooms found bacterial and mold, as did samples of various equipment and parts of the facility. Air sampling showed “1 big mold” as far back as May 29, 2012. Air sampling taken throughout the facility also found mold and bacteria present. Dozens of results exceeded the “action level.” “There was no investigation conducted by the firm when levels exceeded their action limits and

there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacterial and mold) from the facility.”

102. Inspectors also noted in their reports on NECC: Environmental monitoring procedures and practices require sampling. Records showed mold and bacteria. “These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products.”

103. FDA reports indicate there were observations of greenish yellow discoloration lining the interior surface of the viewing lens within the “Inside” autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation and packaging of sterile drug products. The FDA further observed condensation along the interior surfaces of the “Outside” autoclave to collect in a pool at the base of the chamber.

104. The investigators also observed problems with NECC’s ability to maintain its clean room, which is an enclosed space that is supposed to be designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of microbial contamination.

105. The site of NECC’s production facility signaled potential contamination risks and hazards. A used mattress processing facility, also owned by the Conigliaro family, abuts and operates under the same roof as NECC’s drug compounding facility. As the FDA noted in its inspection, “[t]he firm is abutted to the rear and along the left parking area by a recycling facility

that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the [NECC] firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."

106. The FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave located in the firm's Middle Room (purportedly an ISO level 7 space). This autoclave is used for the steam sterilization of formulated bulk drug suspensions. The FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within Weigh Station 3 Hood located in the firm's purported ISO 6 "Clean Room." The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

107. In sum, FDA observed bacteria and mold growing all over the firm's "sterile" facility, one which NECC repeatedly represented to customers was "state-of-the-art" and used to produce "highest quality compounded medications."

108. MSM and/or MSMSW marketed, Ameridose distributed and ARL certified the sterility of the NECC products that were compounded in such deplorable conditions.

**C. THE NECC RELATED DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS**

109. The NECC Related Defendants effectively ignored dozens of complaints and warnings signs of hygiene and sterility problems from as early as April 1999.

110. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. The FDA notified the Massachusetts' pharmacy board in October 2002 about an incident involving a

drug the company had produced, methylprednisolone acetate, which is the same steroid that caused the current fungal meningitis and other associated disease outbreak in 2012.

111. In 2004, an inspection report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid as involved herein.

112. A 2006 letter to NECC from Pharmacy Support Inc., an outside evaluation firm, observed that the company continued to have significant gaps in its sterile compounding operation. That same year the FDA issued warning letters to NECC. NECC and other Defendants received other warnings as well.

113. NECC and the NECC Related Defendants solicited, permitted or facilitated, and/or aided and abetted the solicitation of, out-of-state prescriptions for office use and used unapproved forms. NECC and the NECC Related Defendants were aware of complaints regarding this practice and its improper promotional material and methods, but turned a blind eye to it all.

**D. DEFENDANTS EXPOSED PLAINTIFF TO TOXIN  
CONTAMINATED NECC COMPOUNDED MPA**

114. In 2012, the NECC Related Defendants caused or facilitated vials of preservative free methylprednisolone acetate being shipped to BKC Pain Specialists, LLC's medical practice and facility in Marion, Ohio, including vials from the three lots of contaminated preservative free MPA recalled by NECC. Thousands of other contaminated vials were shipped to scores of other clinics across the country.

115. Massachusetts law and regulations require patient specific prescriptions in order for a Massachusetts compounding pharmacy such as NECC to legally compound, fill and

dispense a medication prescription regardless of the location of the patient or prescriber. Massachusetts law prohibits selling and dispensing compounded medications pursuant to so called “office supply” quantity prescriptions.

116. The NECC Related Defendants were aware of these Massachusetts compounding laws and regulations but negligently, recklessly or intentionally took, authorized, permitted, failed to stop or otherwise aided and abetted NECC’s disregard, violation and circumvention of applicable Massachusetts law and regulations, including instructing or allowing prescribers or health care providers to supply false or fabricated prescription forms in connection with obtain NECC’s compounded MPA and other prescription drugs. In the course of so doing these defendants further agreed expressly, impliedly or tacitly with various health care providers it sold and supplied MPA engage in overt, purposeful and malicious acts that violate or circumvent applicable Massachusetts pharmaceutical law and regulations.

117. Defendants BKC Pain Specialists, LLC and Dr. Katabay are sometimes collectively referred to below as the “BKC Pain Specialists Defendants.”

118. In 2011 and 2012, Pamela R. Cooper was a patient of and underwent the continuous medical care and treatment of the BKC Pain Specialists Defendants in connection with pain due to cervical pain radiating to her shoulders. At all times material herein she was attended to, diagnosed and treated by physicians and other health care providers employed by BKC, including Dr. Katabay.

119. Upon information and belief, during all relevant times, Dr. Katabay co-managed BKC.

120. Upon information and belief, during all relevant times Dr. Katabay participated in BKC's decision to prescribe, purchase for resale, dispense to patients and administer NECC's compounded preservative free MPA to BKC's patients, including Plaintiff Pamela R. Cooper.

121. During all relevant times the BKC Pain Specialists Defendants knew or should have known of the dangers of using compounded preservative free steroid drug formulations instead of such drugs that were manufactured by FDA approved manufacturers, and specifically were aware of or had reason to know of the risks and dangers of using products compounded by NECC. The dangers, hazards and problems entailed in administering compounded drugs, and especially the use of preservative free sterile preparations, were known to the medical profession and the subject of articles and professional guidance documents.

122. NECC competed in the medical marketplace on the basis of offering cheaper prices for MPA and such consideration is believed, and therefore alleged, to have entered into and was one of the factors prompting the BKC Pain Specialists Defendants to purchase NECC's MPA instead of other available steroid preparations or, alternatively, obtaining compounded MPA from local pharmacies where it could have visited, inspected and monitored the quality and safety of the MPA being compounded for use in epidural steroid injection ("ESI") procedures performed by the BKC Pain Specialists Defendants.

123. Despite the existence of professional organizations and societies that provide inspections, assessments and accreditation certifications for compounding pharmacies, NECC was not accredited by any such organization.

124. In connection with BKC Pain Specialists Defendants obtaining NECC's preservative free MPA for its patients, including Plaintiff Pamela R. Cooper, these defendants either failed to take or negligently performed the reasonable and necessary due diligence and

investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's products, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative free MPA for use in ESI procedures, including the neck injection procedures performed on Plaintiff Pamela R. Cooper on or about September 24, 2012 and October 1, 2012.

125. On or about September 24, 2012, and again on October 1, 2012, Dr. Katabay at BKC Pain Specialists' facility performed a cervical steroid injection procedure on plaintiff Pamela R. Cooper, during which procedures plaintiff was administered, according to her medical records, a total of 80mg of NECC's preservative free MPA from one or more vials for each procedure.

126. The MPA used during the ESI procedure was drawn from vials that were part of the three lots of fungus contaminated MPA vials that NECC recalled on or about September 26, 2012 due to fungal contamination traced back to it by the CDC following discovery of the fungus meningitis outbreak.

127. At no time prior to the neck injection procedure on Plaintiff did the BKC Pain Specialists Defendants disclose, advise or inform Plaintiff orally or within its standard preprinted informed consent form that the steroid medication that was going to be injected near her spine was not a medication manufactured by an FDA approved and inspected manufacturer, but rather was a medication that the BKC Pain Specialists Defendants had obtained via mail order from a pharmacy in Massachusetts that was neither inspected by the FDA nor was accredited by any valid accrediting body. Such information is objectively material information to a reasonable patient's decision to undergo an ESI procedure using such medication.

128. Following her ESI procedures on September 24, 2012 and October 1, 2012, the fungus contaminated MPA caused Plaintiff to sustain and suffer injury to her body. She thereafter developed pain and other symptoms, including a stiff neck and headache, which led BKC Pain Specialists to advise her on November 5, 2012 to report to the emergency room to be evaluated for fungal meningitis.

129. Plaintiff Pamela Cooper's medical care and treatment required her being hospitalized or attended to at various out-patient facilities during which she underwent numerous medical tests, including punctures and diagnostic imaging.

130. Plaintiff's injuries and prognosis have caused her, and will in the future continue to cause her, great physical pain and suffering, mental anguish and loss of life's pleasures.

131. Plaintiff has incurred and will in the future incur expenses to obtain medical treatment and care for her injuries and its sequela.

## **V. SUBSTANTIVE COUNTS AGAINST THE NECC RELATED DEFENDANTS AND ARL**

### **COUNT I - NEGLIGENCE UNDER MASSACHUSETTS OR OTHER APPLICABLE STATE LAW**

132. Plaintiffs incorporate by reference all proceeding paragraphs in this Complaint as if fully set forth herein at length, and further allege:

133. As the designer, tester, compounder, seller, marketer, supplier, and/or distributor of consumer products, the ARL and NECC Related Defendants, Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin, owed a duty to the Plaintiffs to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to the Plaintiff.

134. Specifically, but without limitation:

- a. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Plaintiff and her physicians a duty to compound, and provide methylprenisolone acetate that was safe and free of contamination.
- b. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Plaintiff and her physicians a duty to provide reasonable and correct warnings, instructions and labeling to Plaintiff or her physicians.
- c. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Plaintiff and her physicians a duty to properly store and ship methylprenisolone acetate.
- d. ARL owed Plaintiff duties to properly conduct tests to insure that the NECC methylprenisolone acetate was sterile, safe and free of contamination, and to not authorize and prevent its reports from being used in the marketing of products that were not fully tested where and when it knew or had reason to know that was occurring.

135. The NECC Related Defendants breached these respective duties and were otherwise negligent in their design, compounding, formulation, making, creation, sale, testing, marketing and distribution of the recalled MPA steroid medication, which was administered to Plaintiff. These Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, formulator, maker, creator, tester, seller, marketer and distributor of sterile preparations and medications, as licensed to do so by the Commonwealth of Massachusetts.

136. The NECC Related Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, formulation, making, creation, sales, testing, marketing and distributing the recalled MPA in a negligent manner.

137. The NECC Related Defendants further breached their respective duties of care by failing to store, hold and compound the components of the recalled medications; by failing to properly design, compound, formulate, create, make, test, sell and/or distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain facilities where sterile medications were compounded, packaged or stored in a clean, sanitary manner, or taking reasonable steps and measures to assure these functions were performed in clean, sanitary and sterile facilities; by failing to oversee the security and quality control of NECC's or their compounding and distribution facilities; and/or by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by Plaintiff and her physicians.

138. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, formulating, making, creating, testing, marketing, distributing and/or selling preservative free MPA.

139. NECC has been declared insolvent by the Bankruptcy Court presiding over its Bankruptcy Petition and prosecution of any and all actions against it are stayed.

140. In addition to violating the laws of Massachusetts where NECC was headquartered and maintained its facility for compounding, packaging, storing and distributing contaminated and adulterated drugs which were then shipped and distributed to Ohio for administration to patients, including Plaintiff, all or some of the NECC Related Defendants also

violated the Ohio Product Liability Act, including the provision of O.R.C §§, 2307.74; 2307.76, 2307.77 and 2307.78 (A)(1) and (A)(2).

141. The negligence of Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin was a proximate cause of Plaintiff's injuries, harm and losses.

142. As a direct and proximate cause of ARL and the NECC Related Defendants' joint and several acts of negligence, carelessness and recklessness, Plaintiff was exposed to fungal contaminated steroid medication on September 24, 2012 and October 1, 2012 during ESI procedures.

143. As a direct and proximate result of negligence of the defendants identified in this Count, Plaintiff was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

## **COUNT II - NEGLIGENCE *PER SE***

144. Plaintiffs incorporate by reference all proceeding paragraphs in this Complaint as if fully set forth herein at length, and further allege:

145. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Plaintiff a duty under Massachusetts law to maintain the premises of the NECC pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

146. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy “in a clean and sanitary manner[,]” 247 CMR 6.02(1), and free from contamination.

147. As a direct and proximate cause of the Defendants’ Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin’s negligence, carelessness and recklessness by violating these statutory imposed duties, Plaintiff was exposed to fungal contaminated steroid medication on September 25, 2012 during an ESI procedure.

148. As a direct and proximate result of negligence of the defendants identified in this Count, Plaintiff was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

### **COUNT III – NEGLIGENT SUPERVISION**

149. Plaintiffs incorporate by reference all proceeding paragraphs in this Complaint as if fully set forth herein at length, and further allege:

150. ARL and the NECC Related Defendants each respectively had an obligation and duty to exercise due care, and comply with the then existing standard of care to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to make sure the compounded drugs being made, tested, packaged

and stored did not create any harm or risk to Plaintiff and others who received the compounded medications.

151. Defendants Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin each also respectively had an obligation and duty to exercise due care and comply with the then existing standard of care to investigate and hire professional and competent employees or vendors to maintain NECC's production, packaging and storage facility and make sure the purported compounded sterile drugs did not create any harm or risk to Plaintiff and others who received NECC's compounded medications.

152. In breach of these duties, ARL and the NECC Related Defendants failed to exercise due care and failed to supervise their respective employee(s), agent(s) or vendor(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

- a. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly test the steroid medication and these Defendants' were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding this important task and function;
- b. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly compound, sterilize, package, label, store and dispense the steroid medication and these Defendants' were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions; and/or

c. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly review prescriptions for NECC's compounded medications for compliance with applicable prescription laws and/or gave incorrect information or instructions on requisite prescription requirements, and these Defendants' were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions.

d. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly instruct, warn or advise as to the storage, handling and pre-administration administration inspection of NECC's preservative free sterile compounded and/or gave incorrect information or instructions or warnings, and these Defendants' were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions

e. These Defendants were otherwise negligent in hiring, training, and supervising their employees, agents or vendors relevant to this matter.

153. ARL and the NECC Related Defendants knew, or should have known, that their respective employee or agent did not follow proper procedures and precautions and knew or should have known of the risks created by failing to do so.

154. As a direct and proximate cause of these breaches of duty ARL's and the NECC Related Defendants permitted the subject MPA steroid lots to become contaminated and distributed to patients throughout the United States, including Plaintiff.

155. As a direct and proximate cause of ARL's and the NECC Related respective negligence, carelessness and recklessness, Plaintiff was exposed to fungal contaminated steroid medication on September 24, 2012 and October 1, 2012 during ESI procedures.

156. As a direct and proximate result of negligence of the defendants identified in this Count, Plaintiff was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

**COUNT IV – STRICT PRODUCTS LIABILITY: DEFECTIVE MANUFACTURING LIABILITY UNDER THE OHIO PRODUCTS LIABILITY ACT (O.R.C § 2307.74 *ET SEQ.*)**

157. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

158. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin is or are a manufacturer, designer, maker, formulator, distributor, seller, and/or supplier of the NECC MPA sold to and administered Plaintiff.

159. The subject MPA was manufactured, compounded, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin.

160. The NECC MPA was defective in its manufacture and deviated in a material way from its formulation, design specifications and/or performance standards, including but not limited to USP guidelines and requirements, such that it was contaminated with fungi and other toxic or infectious microorganisms, all through no fault of the Plaintiff.

161. The NECC MPA was defective in its manufacture and deviated in a material way from the design specifications and/or performance standards and consequently caused a national

outbreak of fungal meningitis and other serious fungal infection related disorders that are serious, long lasting, permanent or fatal, and very difficult to diagnose and treat.

162. As a direct and proximate cause of the defective condition of the NECC MPA administered to him, Plaintiff was exposed to a fungus contaminated preservative free steroid medication on September 24, 2012, and October 1, 2012 during ESI procedures.

163. As a direct and proximate result of negligence of the defendants identified in this Count, Plaintiff was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

164. Defendant's actions and omissions as alleged in her Complaint constitute a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

**COUNT V – STRICT PRODUCTS LIABILITY: LIABILITY UNDER THE OHIO PRODUCTS LIABILITY ACT FOR INADEQUATE WARNING OR INSTRUCTION (O.R.C. § 2307.76 ET SEQ.)**

165. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

166. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin is or are a manufacturer, designer, maker, formulator, distributor, seller, and/or supplier of the NECC MPA administered Plaintiff, and in such capacity knew or, in the exercise of reasonable care should have known, about the grave and peculiar risks of microbial contamination associated with compounding, dispensing and handling of preservative free compounded sterile preparations in general, and sterile preservative free MPA in particular.

167. Substantially prior to the time that the lots of NECC MPA were recalled in 2012, were produced, packaged, sold and dispensed, the NECC Related defendants knew or had reason to know that NECC had received complaints or reports of adverse problems concerning the purity of its products, including problems with containments in its MPA product.

168. The subject recalled MPA lots were manufactured, compounded, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin without adequate warnings and instructions to enable health care providers prescribing, purchasing, reselling and administering purported preservative free sterile, MPA to properly prescribe, acquire and administer MPA to patients in their practices, such as Plaintiff, which exercising reasonable care a manufacturer or supplier would have provided concerning the risks and dangers of contamination or adulteration of preservative free MPA with toxic and harmful microorganisms.

169. The NECC Related Defendants duty to warn was further prompted and heightened by the deplorable unsanitary and non-sterile conditions of NECC's production facility in Massachusetts where the subject MPA was compounded, packaged, stored and dispensed.

170. As a direct and proximate cause of the defective condition of the NECC Related Defendants, Plaintiff was exposed to a fungus contaminated preservative free steroid medication on September 24, 2012, and October 1, 2012 during ESI procedures.

171. As a direct and proximate result of acts, omissions, activities and negligence of the defendants identified in this Count, Plaintiff was injected with a fungus contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

172. Defendant's actions and omissions as alleged in her Complaint constitute a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

**COUNT VI – STRICT PRODUCTS LIABILITY: DEFECT DUE TO  
NONCONFORMANCE WITH REPRESENTATIONS (O.R.C. § 2307.77 *ET SEQ.*)**

173. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

174. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin is or are a manufacturer, designer, maker, formulator, distributor, seller, and/or supplier of the NECC MPA administered Plaintiff, and in such capacity knew or, in the exercise of reasonable care should have known, about: (a) NECC brand MPA was going to be administered to patients during ESI procedures; and/or (b) the grave and peculiar risks of microbial contamination associated with compounding, dispensing and handling of preservative free compounded sterile preparations in general, and sterile preservative free MPA in particular.

175. The subject MPA administered plaintiff was defective in that, when it left the hands of NECC and Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin, in that it did not conform to representations made by NECC and Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin concerning the (a) purity and safety of the product; (b) compliance or conformity with applicable state, federal or industry requirements or standards, including those issued by USP and other pertinent bodies relating to the purity and safety of the product; and/or (c) the absence of contaminants and adulterants in the product.

176. Plaintiff's physician and the health care facility that he practiced in at the time they selected NECC preservative free MPA to be used during Plaintiff's ESI procedures, justifiably relied upon NECC's and Defendants Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's and/or Glenn Chin's representations that the MPA was pure, conformed to applicable manufacturing standards and practices, including USP standards and requirements, was free of contaminants and safe for use in ESI procedures, and that it would conform to the representations regarding the character and the quality of appropriate preservative free steroid medication for use in ESI procedures. However these representations were not true and indeed were false as the subject MPA dispensed and received by Plaintiff's physician and administered to Plaintiff was contaminated and adulterated by toxic fungus and hence not properly or suitably compounded, packaged, stored and/or dispensed in safe and suitable condition.

177. As a direct and proximate cause of the defective condition of the NECC Related Defendants, Plaintiff was exposed to a fungus contaminated preservative free steroid medication on September 24, 2012, and October 1, 2012 during ESI procedures.

178. As a direct and proximate result of Plaintiff's administration of the subject MPA, and Plaintiff's physician's reliance on NECC's and Defendants Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's and/or Glenn Chin's aforesaid representations, Plaintiff was injected with a fungus contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

179. Defendant's actions and omissions as alleged in her Complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

**COUNT VII – BREACH OF IMPLIED WARRANTY AND TORTIOUS BREACH OF WARRANTY**

180. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

181. The contamination of NECC and other Defendants' methylprednisolone acetate product was present at the time the drug left the NECC facilities' possession and control, rendering the MPA product unfit and unsafe for its intended use as a medication.

182. The contaminated methylprednisolone acetate was not altered in any way after it was sold and dispensed by NECC and other Defendants, and the drug was used as intended.

183. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin breached the implied warranty of merchantability by failing to use reasonable care in compounding, testing, marketing, supplying and/or distributing methylprednisolone acetate.

184. The breaches of implied warranty by Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin of the implied warranties of merchantability were a proximate cause of Plaintiff's injuries, harm and losses as set forth above.

185. As a direct, foreseeable and proximate result of the acts and omissions of the Defendants in breach of the implied warranty of merchantability, and being injected with contaminated methylprednisolone acetate, Plaintiff suffered injuries, conscious pain and suffering, emotional distress, economic loss. The NECC Related Defendants at all time material

were on notice of the breach by virtue of the recall of NECC's MPA products, which breach due to its nature cannot be cured.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

### **COUNT VIII - PUBLIC NUISANCE**

186. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

187. At all relevant times defendants Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

188. Defendants Barry Cadden, Gregory Conigliaro and GDC each owed a duty under Massachusetts law to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination and not create a nuisance.

189. Defendants Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

190. The failure by defendants Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

191. Defendants Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

192. Defendants Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in the laws of the Commonwealth of Massachusetts, 247 CMR 6.02(1).

193. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC caused Plaintiff's injury and losses.

194. As a direct and proximate result of the acts and omissions of Barry Cadden, Gregory Conigliaro and GDC, and being injected with contaminated doses of methylprednisolone acetate, Plaintiff suffered injuries, conscious pain and suffering, emotional distress, economic loss, damages as set forth above.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

#### **COUNT IX-DECEPTIVE TRADE AND BUSINESS PRACTICES ACT VIOLATIONS**

195. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

196. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL engaged in trade and commerce within the Commonwealth of Massachusetts.

197. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL's respective acts of negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act.

198. Defendant Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, and/or Glenn Chin's failure(s) to perform and

fulfill their promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

199. As described herein, defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL represented that NECC's product had characteristics, uses and benefits that it did not have.

200. As describe herein, defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, and/or Glenn Chin represented that the NECC MPA product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

201. As describe herein defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, and/or Glenn Chin dispensed, allowed the dispensing, promoted, solicited and incited the dispensing, and/or aided and abetted the dispensing of NECC's compounded drug products, including MPA, to health care practitioners or facilities on the basis of false, fictitious or otherwise improper or invalid prescriptions in violation of Massachusetts' laws and regulations.

202. As described herein, Defendant ARL improperly provided compounded test results to NECC and defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, and/or Glenn Chin, who in turn used such test results in their scheme to falsely market NECC's MPA and other compounded drug products. At all times material herein ARL knew or had reason to know NECC and defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, and/or Glenn Chin would distribute or disseminate its test results as part

of their marketing effort and either permitted same or failed to take reasonable action to stop such conduct.

203. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL, failed to provide accurate disclosures of all material information before Plaintiff and/or her health providers transacted to use NECC's MPA product.

204. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiff, constituting a violation of the Act.

205. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL's willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

206. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin actively, knowingly, and deceptively concealed their knowledge of the NECC MPA product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

207. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

208. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiff.

209. Defendant Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's, Glenn Chin's and/or ARLs' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to all or some of the following:

- a. Misrepresenting the nature, quality, and characteristics about the product;
- b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety and the dispensing of pharmaceutical products;
- c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and
- d. All other unfair and deceptive acts set forth herein

210. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's, Glenn Chin's and/or ARLs conduct and failures to act, as well as those health care providers and facilities who purposefully and deliberately acted in concert, collusion or conspiracy with these defendants, were unethical and unscrupulous, and caused substantial injury to consumers, including Plaintiff. Defendants engaged in unconscionable actions and course of action.

211. Defendant Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's, Glenn Chin's and/or ARLs conduct and failures to act willfully engaged in the conduct described herein, which they knew were deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

212. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden, Glenn Chin and/or ARL are liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

213. Pre-suit notice of this claim is not required. The NECC Related Defendants in the NECC MDL proceedings, *In Re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419 , Dkt. No. 1:13-md-2419 (FDS) (D. Mass)), have agreed to waive pre-suit notice requirements, including MGL c. 93A's pre-suit demand requirement. The waiver is documented in Case Management Order No. 6 entered in MDL No. 2419 on June 28, 2013. ARL does not maintain a place of business or keep assets within the Commonwealth of Massachusetts.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

**COUNT X- CONCERTED ACTION AND CIVIL CONSPIRACY**

214. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

215. The NECC Related defendants acted in cooperation and in concert with each other in committing their respective tortious acts in furtherance of their respective interests, including profit and revenue interests.

216. The NECC Related Defendants explicitly, impliedly or tacitly entered into a conspiracy to wrongfully and tortiously market NECC's compounded medications in bulk instead of medications manufactured and distributed by bona fide FDA approved manufacturers and/or obtaining compounded medications through patient specific prescriptions prior to filling and dispensing of the prescription as required under Massachusetts law where the prescriptions were filled and dispensed

217. Each defendant understood the general objectives of the scheme, accepted them, and agreed to do its part to further them in furtherance of their respective economic interests.

218. Each Defendant purposefully engaged in the overt acts described above in furtherance of their scheme.

219. As co-conspirators each defendant is liable for the acts, omissions and activities of the other co-conspirators in furtherance of the conspiracy, including those which harmed the Plaintiffs.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

#### **COUNT XI – PUNITIVE DAMAGES**

220. The NECC Defendants' conduct and omissions stated above constitutes gross negligence, purposeful and deliberate misconduct, and/or a reckless disregard for human life and safety on their respective parts, thus warranting the imposition of punitive damages.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

**VI. SUBSTANTIVE COUNTS AGAINST THE BKC PAIN SPECIALISTS DEFENDANTS**

**COUNT XII – MEDICAL NEGLIGENCE**

221. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

222. For many months prior to the September 24, 2012, and October 1, 2012 injections that are the subject of this Complaint, Plaintiff placed herself in the professional care of Defendant Dr. Katabay and BKC Pain Specialists, LLC, as well as the physicians, nurses, technicians, medical staff, medical professionals, employees, agents, independent contractors, businesses, corporations, or other entities associated with and/or providing services at BKC Pain Specialist, LLC's pain management facility and practice, and in the course of same Plaintiff contracted with them for appropriate professional diagnosis, attention, and treatment. Specifically, Plaintiff contracted with and presented to Defendants Dr. Katabay and BKC Pain Specialists, LLC for treatment of her pain.

223. During all relevant times, Defendant Dr. Katabay held himself out as a skilled and practicing physician specializing in pain management and the performance of medical procedures to alleviate pain and discomfort conditions such as Plaintiff suffered and sought treatment.

224. During all relevant times, Defendants BKC Pain Specialists, LLC held itself (or themselves) out to the public and to Plaintiff as a medical practice and health care facility comprised of skilled, knowledgeable, competent and able practicing physicians specializing in both pain management and the performance of medical procedures to alleviate pain and discomfort conditions such as Plaintiff suffered and sought treatment.

225. As physicians of a medical practice, Defendants Dr. Katabay and the other members and professional staff of BKC Pain Specialists, LLC are and were all required to use their knowledge and skill in a manner consistent with the knowledge and skill possessed by other physicians practicing in the same field of practice, in the same or a similar locality, and at the same time.

226. The physicians, nurses, technicians, medical staff, medical professionals, employees, agents, independent contractors, businesses, corporations, or other entities associated with and/or providing services at BKC Pain Specialists, LLC are and were required to use their knowledge and skill in a manner consistent with the knowledge and skill possessed by other medical professionals and staff in the same field of practice, in the same or a similar locality, and at the same time.

227. Defendant Dr. Katabay and/or other physicians, nurses, technicians, medical staff, medical professionals, employees, agents, independent contractors, businesses, corporations, or other entities associated with privileges at and/or providing services at BKC Pain Specialists, LLC negligently selected NECC preservative free MPA for use in ESI procedures.

228. On information and belief based on the timing of her procedure and statements appearing in her medical records, Plaintiff believes, and therefore alleges, that the BKC Pain Specialist Defendants acquired supplies of MPA from NECC and/or the NECC related Defendants. The nature and timing of the prescriptions for the MPA administered to him in relation to her injections on September 24, 2012, and October 1, 2012, are not reasonably known to Plaintiff and are hence an issue in this matter on which liability may exist and attach.

229. The BKC Pain Specialist Defendants knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.

230. The BKC Pain Specialists Defendants knew or had reason to know and should have about the deplorable sanitary conditions of NECC's production facility in Massachusetts at the time it acquired and administered the subject contaminated MPA to Plaintiff.

231. The BKC Pain Specialists Defendants negligently and recklessly purchased contaminated MPA from NECC.

232. The BKC Pain Specialists Defendants failed to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase preservative free MPA from NECC.

233. The medical care provided to the Plaintiff by the BKC Pain Specialists Defendants, acting as aforesaid, fell below the applicable standard of care required of practicing physicians as set forth in the Affidavit of Dr. Matthew Lee, MD, RPh, MS provided pursuant to Ohio Civil Rule 10(D)(2) to be filed with amended complaint.

234. More specifically, the BKC Pain Specialists Defendants were negligent and rendered substandard care in, among others, the following respects, upon information and belief:

- a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
- b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;
- c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;

- d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;
- e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;
- f. failed to determine whether NECC had a history of adverse events, complaints, and/or product liability suits before procuring spinal injection medicines from that company;
- g. failed to keep abreast of the dangers of sterile compounding and recommended and practices relating to acquisition and administration of compounded sterile products, and especially preservative free versions of medications such as the MPA involved in this case;
- h. failed to heed and apply prudent and recommended and practices;
- i. purchased compounded injectable steroids from an unaccredited compounding pharmacy;
- j. failed to implement policies and procedures that would prevent procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of adverse events and product liability suits;
- k. injected steroids into Plaintiff's spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with pathogens;

- l. injecting steroids into Plaintiff's neck during injection procedures without taking reasonable steps to determine whether the medication administered was safe and suitable for injection into Plaintiff;
- m. failing to properly inform Plaintiff prior to administration the medication being injected into him was not manufactured by an FDA approved manufacturer, but rather was acquired from an out of state compounding pharmacy that is not licensed by or inspected by the FDA; and
- n. Failing to properly and fully advise Plaintiff of the material risks and dangers inherent and potentially involved in using NECC's compounded preservative free MPA instead of other available medication alternatives when obtaining informed consent for the neck injection procedure.

235. As a direct and proximate result of the negligence of Dr. Katabay and/or the physicians, nurses, technicians, medical staff, medical professionals, employees, agents, independent contractors, businesses, corporations, or other entities associated with and/or providing services at BKC Pain Specialists, LLC, Plaintiff has suffered, continues to suffer, and will suffer in the future injuries, damages and losses as set forth above.

236. The BKC Pain Specialists Defendants' conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

### **COUNT XIII – LACK OF INFORMED CONSENT**

237. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

238. The BKC Pain Specialists Defendants failed to properly and fully advise Plaintiff of (a) their intention to use and administer a compounded preservative free medication made and dispensed by NECC; (b) that NECC was not accredited by any valid accrediting organization; (c) that the medication to be used in the procedure was not manufactured by an FDA licensed and approved pharmaceutical manufacturer; and/or (d) the material risks and dangers inherent and potentially involved in using a compounded preservative free steroid preparation which had not been approved by FDA, such as the contamination or adulteration of the medicine with pathogenic microorganisms, when they sought and obtained Plaintiff's informed consent to the neck injection procedures.

239. A reasonable person in the position of Plaintiff would have decided against undergoing the neck injection procedures at the BKC Pain Specialists Defendants' facility in Marion using compounded a preservative free steroid medication had the full material facts and risks, including the forgoing, been disclosed and explained prior to the procedure.

240. The material undisclosed risks and dangers of using a compounded preservative free steroid medication, including the material risk the medication could be contaminated by toxic or infectious microorganisms, actually materialized when Plaintiff was administered NECC's fungus contaminated MPA during her neck injection procedures on or about September 24, 2012, and October 1, 2012.

241. Had the BKC Pain Specialists Defendants properly and fully informed patients such as Plaintiff, a reasonable patient would have decided against the neck injection therapy using the NECC compounded medicine the BKC Pain Specialists Defendants decided to acquire and administer into Plaintiff.

242. As a direct and proximate result of the failure of Dr. Katabay and/or the physicians, nurses, technicians, medical staff, medical professionals, employees, agents, independent contractors, businesses, corporations, or other entities associated with and/or providing services at BKC Pain Specialists to obtain a valid informed consent of Plaintiff prior to the neck injection procedures, Plaintiff has sustained injury to her person and suffered, continues to suffer, and will suffer in the future injuries, damages and losses as set forth above.

243. The BKC Pain Specialists Defendants' conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

## **VII. SUBSTANTIVE COUNTS AGAINST ALL DEFENDANTS**

### **COUNT XIV - LOSS OF CONSORTIUM CLAIMS ON BEHALF OF SPOUSE PLAINTIFF DAVID L. COOPER**

244. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, further allege:

245. At all times material herein Spouse Plaintiff, David L. Cooper, was and still is married to Plaintiff Pamela R. Cooper.

246. As a further direct and proximate result of the defendants' negligence, breach of warranty, and other culpable acts, omissions and activities set out above, Spouse Plaintiff, David L. Cooper, has suffered the loss of his wife's services, companionship, society, and consortium, emotional distress and mental anguish, and he will continue to suffer such loss and damages in the foreseeable future.

247. Spouse Plaintiff also has incurred and will incur expenses relating obtaining medical treatment and care for his wife's injuries.

**WHEREFORE**, the Plaintiffs demand judgment against Defendants, jointly and severally, as set forth below in the Prayer for Relief.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment against Defendants, jointly and/or severally, as follows:

- (a) That Plaintiffs be awarded compensatory damages;
- (b) That Plaintiffs be awarded punitive damages;
- (c) That Plaintiffs be awarded pre-judgment interest;
- (d) That Plaintiffs be awarded reasonable attorneys' fees and costs; and
- (e) That Plaintiffs be awarded all other legal and equitable relief to which they may be entitled.

**JURY DEMAND**

Plaintiffs hereby demands a trial by jury.

**Respectfully Submitted,**

**PLAINTIFFS PAMELA AND DAVID COOPER,**

**By Her Attorneys,**

/s/ Pamela Borgess

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